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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,806	07/17/2003	Sylvia Daunert	50229-378	8451

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,806	DAUNERT ET AL.	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 8-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group II, claims 6 and 7, in the paper filed 21 August 2006 is acknowledged. The traversal is on the ground(s) that the aequorin molecule used in the broadly claimed assays is generic and that the various mutant species could be searched together therewith. This is not found persuasive because the inventions remain distinct for the reasons of record regarding the product and process of use relationships and the distinctness of the mutually exclusive structurally different mutants and because applicant has elected claims to a product limited to one of the mutants. The requirement is still deemed proper and is therefore made FINAL. Applicant's statement regarding rejoinder is noted. Claims 1-5 and 8-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no (allowable) generic or linking claim.

The disclosure is objected to because of the following informalities: page 14, line 9, the superscript "17" should be replaced with the citation --Grabarek...-- as on page 23. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant suggests a method and kit using reagents comprising primary and secondary antibodies specific for 6-keto-prostaglandin $F_{1\alpha}$ and an aequorin-6-keto-prostaglandin $F_{1\alpha}$-conjugate (see e.g. pages 10 or 12). However, applicant provides no description or guidance for how one makes or uses such reagents in a detection method or kit. Instead, applicant teaches a method using reagents comprising primary antibodies specific for 6-keto-prostaglandin $F_{1\alpha}$, an aequorin-6-keto-prostaglandin $F_{1\alpha}$-conjugate, and secondary immobilized anti-immunoglobulin antibodies (see e.g. pages 13 or 15). Absent further written description and guidance from applicant one would not be assured of the ability to make and use the invention as instantly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6 and 7, the interrelationships of the components are not clear, e.g. it is not clear what is intended by a secondary primary antibody.

In claim 7, the recitation that the conjugate is a mutant of aequorin is not clear, perhaps applicant intended that the aequorin of the conjugate is a mutant or that the conjugate comprises an aequorin mutant.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim 6 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Pradelles et al. (Anal. Chem. 57: 1170, 1985) in view of any of Kosak (US 4,604,364), Stults (US 5,486,455), or Liotta et al. (US 5,942,407).

Pradelles et al. teach a competitive immunoassay for determination of 6-keto-prostaglandin $F_{1\alpha}$ on microplates. The assay utilized antibodies specific for 6-keto-prostaglandin $F_{1\alpha}$, enzyme-labeled 6-keto-prostaglandin $F_{1\alpha}$, and immobilized anti-immunoglobulin antibodies.

The reference teaches enzyme labels as an alternative to radiolabels. In contrast to the invention as instantly disclosed, the reference does not teach aequorin labels.

Any of Kosak, Stults, or Liotta et al. teach aequorin as an alternative label to radiolabels or enzyme labels in immunoassays.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have substituted an alternative label such as aequorin, as taught by any of Kosak, Stults, or Liotta et al., in the assay of Pradelles et al. in view of the direct suggestion in the references of any of Kosak, Stults, or Liotta et al. to use aequorin as a label to replace radiolabels or enzyme labels in immunoassays. It would have been obvious to formulate the reagents of Pradelles et al., as modified, into a kit since that is conventional for convenience, economy, and reproducibility.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pradelles et al. (Anal. Chem. 57: 1170, 1985) in view of any of Kosak (US 4,604,364), Stults (US 5,486,455), or Liotta et al. (US 5,942,407) as applied to claim 6 above, and further in view of Lewis et al. (Bioconjugate Chem. 11: 65, 2000).

The teachings of Pradelles et al., Kosak, Stults, and Liotta et al. are as set forth above and differ from the invention as instantly disclosed as not teaching a cysteine-free mutant of aequorin.

Lewis et al. teach a cysteine-free mutant of aequorin for use as a label in binding assays.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have substituted a recombinant aequorin, as taught by Lewis et al., in the assay and kit of Pradelles et al., as modified, in view of the direct suggestion in the reference of Lewis et al. to do so because of the greater bioluminescence activity of the mutant compared to the wild-type aequorin.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lüke et al. (J. Immunol. Meth. 148: 217, 1992) teach labeling of prostaglandins with a biotin-avidin bridge for use in immunoassay.

Desai et al. (Anal. Chem. 74: 3892, August 2002) teach the invention essentially as disclosed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James L. Grun, Ph.D.
November 3, 2006

LONG V. LE 11/08/06
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